GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2383
ANSWERED ON:15.12.2004
CLINICAL TRIALS ON HUMAN BEINGS
Kaswan Shri Ram Singh

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Clinical Trials on Human Beings are not permitted in the country ;

(b) if so, the facts of the matter in this regard ;

(c) whether the Multinationals are conducting trials without permission and without following the norms ;

(d) if so, the details thereof ; and

(e) the details of permission granted for Clinical trials to Multinational Companies during the current year?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) & (b) Clinical trials on human beings are permitted in case of New Drugs defined under Rule-122E of Drugs & Cosmetics Act as per the prescribed norms. The applicants are also required to obtain Ethics Committee approval of the concerned Institution and strictly follow the norms prescribed under Good Clinical Practice(GCP) guidelines and Ethical Guidelines for Biomedical Research on Human Subject etc. In case of clinical trials involving Biotech drugs approval of Genetic Engineering Approval Committee (GEAC) under Ministry of Environment & Forests is also required.

(c) to (e) 45 clinical trial permissions have been granted in the current year to the multinational companies, as per norms prescribed in Drugs & Cosmetics Rules.